EXHIBIT E

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions

MDL No.
15-2666 (JNE/FLM)

VIDEOTAPED DEPOSITION

OF

MARK ALBRECHT

VOLUME 1

Minneapolis, Minnesota

Friday, October 7th, 2016

Reported by:
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THE VIDEOTAPED DEPOSITION OF MARK ALBRECHT, VOLUME 1, taken on this 7th day of October, 2016, at the Law Offices of Blackwell, Burke, LLP, 431 South Seventh Street, Suite 2500, Minneapolis, Minnesota, commencing at approximately 9:17 a.m.

P R O C E E D I N G S

THE VIDEOGRAPHER: This is the start of tape labeled number 1 in the videotaped deposition of Mark Albrecht in the matter of In Re: Bair Hugger Forced Air Warming Products Liability Litigation, in the U.S. District Court, District of Minnesota. The MDL case number is 15-2666 (JNE/FLN).

This deposition is being held at Blackwell, Burke law firm in Minneapolis, Minnesota on October 7th, 2016. The time is 9:18 a.m. My name is Kraig Hildahl, I'm a legal video specialist from TSG Reporting. The court reporter is Amy Larson also with TSG Reporting.

Will counsel please introduce themselves for the record.

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Q. Absolutely.

MR. C. GORDON: What we'll do is we'll take a break and print out clean copies.

THE VIDEOGRAPHER: We're going off the record at 12:34 p.m.

(Whereupon, a brief recess was taken.)

THE VIDEOGRAPHER: This is video number 3 in the deposition of Mark Albrecht. Today is October 7th, 2016. We're going back on the record at 1:02 p.m.

BY MR. C. GORDON:

Q. Before we went off the record we were starting to talk about the Exhibit 8, which was one of your papers and the one that had the observational study component to it --

A. Yup.

Q. -- right?

And I want to focus on the observational component right now --

A. Okay.

Q. -- and talk about the other stuff later.

You -- you obtained the data from

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Dr. Reed, right?

A. The hospital he's at, yes.

Q. Okay. When -- when did you first meet Dr. Reed?

A. I can tell by the papers here what a date would be, but I'm guessing around 2010 would the first time we met up, something like that, 2009. I wish I could tell you exactly. That stuff is kind of fuzzy for people. I'm not a big date rememberer --

Q. And -- and --

A. You probably figured that out by now.

Q. I'm not looking for precision, just how did -- how you meet him?

A. Well, there's a network of folks that do research in patient warming and people have interest in it, so just kind of pinging around here and there and people know each other and he got introduced to us. Maybe it was through Scott Augustine, I believe. That's probably who made the introduction. But I could be wrong, it could have been some other path too. It's kind of one community.

Q. Where -- where did you first meet him, in

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England, the U.S.?

A. Probably the U.S. I think -- boy, I'm trying to get the order of events, did I go out there first to meet with him or did he come here. I would guess he probably came here first.

Q. The -- the study that's in Exhibit 8, that's got the two components to it --

A. It does.

Q. -- from the outset was it planned that there would be two components or did it start out as one and the other one was added?

A. That's a great question. As we were kind of embracing the problem and thinking it through wondering what would we need in terms of data that's available and what would we like to assess, this was brought up as something that was of interest, the observational component.

We definite -- definitely planned to look at the airflow characteristics in a laminar theater in some of the higher-performing ones like the UK has, so that was thought of. And I think -- I -- I think Mike Reed brought the infection data to

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the table that he had, some of that available, and he would like to look at that too just to see how it kind of all painted together in a picture.

Q. Did you go over to England for the actual -- the airflow study part of it?

A. Yes.

Q. At -- at that point when you were in England for that part, was it already contemplated that you would be doing the observational study on the infection data?

A. In all truthfulness, I don't know when that came in.

Q. Okay.

A. That's a big e-mail log, huh?

Q. It is.

(Whereupon, Exhibit 10 was marked for identification.)

BY MR. C. GORDON:

Q. Exhibit, what is that, 10?

MR. B. GORDON: Ten.

THE WITNESS: What is this? Oh, this is the data, okay.

MR. B. GORDON: So you can read

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Q. -- whatever you need to consult to --
A. Looking here, yes, July.
Q. The data you had available to you started in October of 2007, right?
A. I don't know, because I don't have the exact data in front of me that was used. I've been given this table telling me that this is it.
Q. The Exhibit 10, I will represent to you was produced by Augustine -- I don't know if it was Dr. Augustine personally, but I think it was Augustine Medical, pursuant to a subpoena.
A. Uh-huh. Did that come from the test report folders, was that the actual analysis file?
Q. Electronically I have no idea.
A. Because that's very important to know, because that would govern why the decisions for the time periods are what they are.
Q. Tell me the two different files you said.
A. So there was a file that was used for analysis that was agreed upon by the group. So there's -- there's actual statistical code that runs this and there's data that underlies that. And for me to be certain on

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anything that's going on, I would need access to that.

MR. B. GORDON: Well, and I -- for that reason I'm going to interpose an objection to the reliability of this chart, Exhibit 11, prepared by your paralegal and you, as being an adequate and fair representation of the statistical data that would be comprised in Exhibit 10. I just want a standing objection to the use of this, because I don't know that it's the same thing.

THE WITNESS: That's -- I see the date in this and I'm not sure what that's about.

MR. C. GORDON: I think we're talking about two different things.

Ben, to the extent you -- you know, I mean, we prepared Exhibit 11, and if there are any discrepancies between it and --

MR. B. GORDON: Right, because he can't authenticate anything in --

MR. C. GORDON: He can't authenticate Exhibit 11, clearly.

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BY MR. C. GORDON:
Q. Do you recall looking at data in the form of an Excel spreadsheet?
A. Yeah, at some point something came over as an Excel spreadsheet that we started from.
Q. And as you sit here today, you don't have any recollection of whether there was or was not data provided to you prior to July 1st, 2008?
A. I don't know. I have no recollection on that detail.
Q. Okay. So would it be -- let's see if this jogs your memory. If you -- if you -- if you look at either Exhibit 10 or 11, although 11 is a lot easier --

MR. B. GORDON: Just give me a standing objection to 11 and then you can use it, if he can make sense of it, that's fine.

BY MR. C. GORDON:
Q. Yeah, and -- and -- what I'm going to -- all I'm doing this is to -- to -- to jog your memory, you know, I'm not -- I'm not asking you to authenticate about what I'm about to say. But if you were to count the number of -- of infections that arose within 60 days

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of the operating procedure, which was the criteria used, right?
A. I believe so. I'd have to look through here and what was sent to me for the data and the definitions. Hold tight. Again, without the exact code in front of me, it's very hard for me to faithfully answer some of these questions, because if they're very detail oriented, I sometimes won't be able to tell you because I just simply don't know the detail. Let's see here. (Reviews document.) Okay. "In order to standardize a duration of follow-up, only infections presenting within 60 days of surgery were included," okay. Yup.
Q. And, again, I'm not asking you to -- to verify this or refute it or anything, but if you were to count from Exhibit 10 --
A. Okay.
Q. -- which it's a lot easier to do on Exhibit 11, the number of procedures performed at Wansbeck between October 1st, 2007, and June 30th, 2008, the total number of -- of hip and knee prostheses -- or joint

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there were three infections that -- that met the criteria, correct?

MR. B. GORDON: Could you reread that? I'm sorry, I missed it. I can read it right here, that's okay.

THE WITNESS: It's based on the table, yes, I have three infections.

MR. C. GORDON: Okay.

BY MR. C. GORDON:

Q. Now, if you would look at Exhibit 11.

A. Okay.

Q. And, again, feel free to cross-reference to Exhibit 10.

MR. B. GORDON: Standing objection.

BY MR. C. GORDON:

Q. If you count the infections for that time period --

A. Okay.

Q. -- June 1st, 2010, to 12/31/2010, there are actually four, correct?

A. I would have to physically count these, but that's not what our data says here. The data set that was analyzed there was three.

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Q. Go ahead and count.

A. I see one in this article --

Q. Be sure you look at the --

MR. B. GORDON: June --

BY MR. C. GORDON:

Q. I think there's -- I -- I start at the very end of the study period, so look --

A. Okay. I've got one here on 10/30/07.

Q. No --

A. I'm sorry.

Q. -- I'm sorry, we'll get to those. If you jump ahead to -- I guess they're not page-numbered, but way in where it's -- where sort of towards the very bottom of the page it starts with 6/1/2010 there.

A. Okay.

MR. B. GORDON: Unfortunately, the pages aren't numbered.

THE WITNESS: Okay. So 6/1. So we got one, two, three. Yeah, I count four, and the fourth one occurring on 11/22/10.

MR. B. GORDON: Just, again, I want to object to the extent that we can't know definitively that this is an accurate

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reflection of what's actually in the data set, because it's not from the data set or it's an extraction from counsel from the data set.

BY MR. C. GORDON:

Q. Yeah, and for the four infections, if you -- you know, go ahead and look at --

A. Well, that's what I was going to say, because there may have been a reason --

Q. Yeah, and that's exactly why -- if there's a reason, I'd like to know. That's --

A. And I -- honestly, in those calls I probably sent the e-mail to Mike or Paul about someone on this and there was a determination, but it's so long ago you can't tell.

(Reviews document.)

Yeah, I don't know. I can't tell if anything on here gives me any insight into this.

Q. Let's see if this jogs your memory about --

A. Please.

Q. -- issues.

(Whereupon, Exhibit 12 was marked for identification.)

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BY MR. C. GORDON:

Q. I'm showing you Exhibit 12. And this is some -- a document you produced, a series of e-mails between you and Dr. Reed from 2012, right?

A. Yeah.

Q. Or two -- so I guess 2011, 2012.

A. So we start at the back, forward here.

Q. It looks like it. In fact, let's start at the -- at the back page, which --

A. Yeah, please.

Q. -- the first e-mail where -- and the subject says, "Hi, Mike. Say, the data file you sent me doesn't match the earlier one for overlapping cases"; do you see that?

MR. B. GORDON: Which page are you on?

MR. ASSAAD: Which page are you looking at?

MR. C. GORDON: The Bates number 3576.

MR. ASSAAD: Which e-mail? The last page?

MR. C. GORDON: It's the last

e-mail, but it starts at the bottom of the second page or second to last page.

MR. B. GORDON: The subject says, "Hi, Mike."

THE WITNESS: "Mike, I've done a quick analysis of the new data trends"; is that what you're looking at?

MR. C. GORDON: Yes.

BY MR. C. GORDON:

Q. And you say, "The data files are not totally consistent in regards to the data that the BR, JB, JS article was based upon."

That -- that's a reference to Exhibit 8, right?

A. Okay. So this e-mail is after the analysis of this, yes.

Q. Okay. And the second to the last paragraph of your first e-mail that starts this chain is you -- you tell Dr. Reed, "So I'm giving you a graphic for the Wansbeck data, but do not distribute it for it," quote, "Slightly," close quote, "Conflicts with study data due to different reporting practices in your data. The relevant info supported in your

figure is," and then you go on to give odds ratios, confidence intervals.

Does this reflect -- refresh your recollection that you had seen data that you thought slightly conflicted with the study data?

A. Well, we did an analysis on the file that went into here, right, and then we got a new file that he wanted updated statistics on after the article was published and everything was done. And it looks like it didn't line up a hundred percent, so I ran the analysis, I'm not sure what's going on, and that's kind of where this thread comes from.

Q. And I want to make it very clear, I have no idea if Exhibit 10 is the original data --

A. I don't either.

Q. -- or the -- the newer data that's slightly conflicted.

A. It's probably the slightly conflicted, because this one would match up, whatever it is.

Q. Okay. Going back to what you report for the

number of infections of Bair Hugger only study period --

A. Okay.

Q. -- in -- on Exhibit 8, and I think that's on page 1542, you report 31 -- 32, correct?

A. Excuse me. Okay. So patient-warming device, infections, developing infection for forced air, 32.

Q. Okay. And you're more than welcome to take the time to do that, but my -- I -- I count in that Bair Hugger only period on the data on Exhibit 10 that there were actually 31 infections in -- at Wansbeck.

A. All right.

Q. As you -- again, as you sit here today --

A. I don't know.

Q. I guess -- well, number one, you can go back and look at Exhibit 12. You did a recalculation of the odds ratio --

A. With the updated data, yes.

Q. Yeah, and --

A. That would be different than the data here.

Q. Right. What was the odds -- what was the odds ratio as you reported in the paper?

A. Okay. So the paper odds ratio was 3.8 with a confidence interval of 1.2 to 12.5.

Q. Okay.

A. And the updated one here had an odds ratio of 2.98, and a confidence interval that's still significant.

Q. So the odds ratio going down --

A. It did.

Q. -- would be -- would be consistent with too high a number on the Bair Hugger side and too low a number on the HotDog only side, right?

A. There's not too high a number, too low a number. The data file that was assessed that was screened by the clinicians, these are the numbers that represent it.

Q. I -- right. I didn't mean to say a mistake was made. I'm saying that the -- the difference between 3.8 and 2.9 --

MR. B. GORDON: Eight.

BY MR. C. GORDON:

Q. -- 8, could be accounted for by having lesser infections in the forced -- in the Bair Hugger only period and more infections in the HotDog period, correct?

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A. It could be due to a reduction in Bair Hugger infections, HotDog stays the same. It could be due to an increase in HotDog infections, Bair Hugger stays the same. You know, there's many ways to get an odds way to move.

Q. And but the odds -- if -- if in fact there were -- the data you analyzed the second time around had fewer infections in the HotDog period and more infections in the Bair Hugger -- sorry. Strike that.

A. The infections could have been the same, the number of controls could have changed, so we have fewer -- more non-infections and that's going to push it down, because you're looking at odds ratios.

Q. But one way that the odds ratio might have changed is if the total number of infections attributed to the Bair Hugger only period went -- was lower and the total number of infections attributed to the HotDog only period was higher?

MR. B. GORDON: Objection to form, calls for speculation, not supported by the facts in evidence.

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THE WITNESS: If you add infections to the one group and not to the other, you will move the odds ratio.

MR. C. GORDON: Okay.

THE WITNESS: There's about four different mechanisms to push it in different directions.

MR. C. GORDON: Right.

BY MR. C. GORDON:

Q. And I -- I don't want to spend a lot of time, you know, on 31 versus 32 or 3 versus 4, I just --

A. Sure.

Q. -- does that --

A. Yeah, they paid me to -- this is after my time. I was out at a new job. They wanted the file updated, so I did that for them using the same methods with the new data file, and this is what was returned.

Q. Okay. Are you aware of any letters to the editor or any efforts undertaken to correct the odds ratio that was reported?

MR. B. GORDON: Object to form.

THE WITNESS: This isn't a

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correction needed, because the new data was added, so the cohort is different in this versus what's in the paper. So the new data and the trend does persist. So Mike is asking, "I'm keen to see what's happened since we looked at this last, so there's an old file attached in case you don't have it and the new data." So he augmented the data set and that's why there's the different number.

MR. C. GORDON: Okay.

BY MR. C. GORDON:

Q. So what -- what was it that's slightly conflicted with the study data?

A. I have no clue. I've got to look at this very carefully. (Reviews document.)

So it looks like in the new file they sent me there was that 60 days concern. He didn't have a date, so he couldn't clip it in the same manner, and I think that was part of it.

So he sent me a file that wasn't as complete as the one we initially used and it was missing one of the fields we did to

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figure out the number of infections, and so this was just an internal update for him.

This wasn't reanalysis of the original study. This was just, Hey, Mark, I've got a data file here, I wanted to see for my own knowledge if this trend is persisting given a little more data, could you help me out.

Q. Did you write up a paper that had a revised analysis or an updated analysis of the additional data?

A. Yeah, and it was in my -- let's see here. You guys should have got that somewhere. In my Gmail dump I would have expected it, but this might not have come from Gmail, this might have been from my U of M account, which is toast.

Q. What do you mean it's toast?

A. It doesn't exist anymore, so in doing the document pull I couldn't get anything from there.

Q. Okay. Well --

A. Do you have that updated study document? I would be happy to walk you through it and try

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Q. That -- and it's your study that's cited there, right?
A. Uh-huh.
Q. Do you -- you said people can do what they want with the data, but do you think that what you see here in Exhibit 13 is scientifically supported by your study?
A. In an observational sense, yes, it is, those are the numbers for the periods. This isn't the result of a randomized clinical trial. I don't know what constitutes sufficient data for marketing. A lot of people use data in different ways.
Q. Can you -- do you believe your study can in any way be used to support the conclusion that switching from Bair Hugger to HotDog will reduce surgical site infections?
MR. B. GORDON: Objection to form, asked and answered, calls for a medical conclusion.
THE WITNESS: There's observational data in here that shows a decrease in infection rates with the switch between devices, that is true, that is

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confounded with antibiotics.
BY MR. C. GORDON:
Q. It's also confounded with prophylaxis -- thromboprophylaxis?
A. Yes. It's observational in nature.
Q. And if you eliminate just those two confounders, there is no statistical -- statistically meaningful difference --
MR. B. GORDON: Objection to form.
BY MR. C. GORDON:
Q. -- between Bair Hugger and HotDog, right?
A. This is not a randomized clinical trial. I don't know what effect led to what.
MR. B. GORDON: Object to form, misstates his testimony.
THE WITNESS: This is observational data.
BY MR. C. GORDON:
Q. Why do observational data? What's -- what's the purpose?
A. It's to identify trends that you may suspect in the data and bring it to question so someone can do a proper experiment further on, like a randomized trial.

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Q. Your trendline was just an arithmetic mean across 23 months --
A. Uh-huh.
Q. -- right?
What -- having gone through the exercise that you've gone through now to compare one time period, just the Rivaroxaban versus the no Rivaroxaban, would you agree that a trendline that shows an arithmetic mean across the -- that entire time period is pretty misleading?
MR. B. GORDON: Objection to form.
THE WITNESS: I would have liked to have added that to the effects here so it's more clear what that did over the time period. Having you make me drill into it a little more clearly like that and not treat it as just a confounder that, well, it's there, so you can't truly trust this, you know, I would have dug in a little deeper and put an effect in the table, I think.
BY MR. C. GORDON:
Q. And if you had done that, tell me what -- would that -- would you have been able to do

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a multivariate analysis with that, is that the right term?
A. I still don't think we would have. I think we would have presented it that we looked for this effect, saw nothing, we looked for that effect, saw nothing, oh, antibiotics had an effect, forced air had an effect, now we need to figure this out with a trial.
So you'd do this in a univariate fashion still with observational data, in my opinion.
Q. If you were to analyze the data factor -- taking into consideration antibiotics and the -- the Rivaroxaban, and -- and, in effect, factored those out, do you still think that there would -- even with observational data it would show a difference between Bair Hugger and HotDog?
MR. B. GORDON: Objection to form, misstates his earlier testimony.
THE WITNESS: I don't know. I would have to run a model. There's a period of time here which comes into play. This data, there's possibly not enough

infections -- infections to do a multivariate analysis like that where it's properly powered, just kind of looking at this. I'm not so sure we'd be able to tease out the effect of multiple factors at the same time with a data set that has, you know, few infections like that over multiple cuts of variables. So that can be difficult. You'd have to try.

BY MR. C. GORDON:

Q. Well, you'd agree with me that what we just teased out with just those two -- two variables, the antibiotics and the anti-thrombophylaxis -- thromboprophylaxis, resulted in two periods that were pretty comparable in both in duration and in number of procedures, right?

A. Yeah. I'd like to add that to a table as a univariate effect and do further experimentation to see what led to what.

Q. One of my associates grew up in California.

A. Sure.

Q. And in his -- his fond young -- young childhood memory is his family going to

Disneyland and his brother leaning over to him as they were driving to Disneyland and said, "Everybody who goes to Disneyland dies."

A. Okay.

Q. That's actually true, right?

A. All right. How is that relevant to this?

MR. B. GORDON: Object to the form of the question.

BY MR. C. GORDON:

Q. Well, you'd agree that it would be absurd to conclude from the fact that everybody who goes to Disneyland dies, that Disneyland has anything to do with people dying?

MR. B. GORDON: Object to form, calls for speculation, improper hypothetical.

THE WITNESS: I can't tell you from observational data if it's in change in device or if it's a change in antibiotics clearly, because other things are going on behind the scenes. This is a hypothesis. It's presented as such that there are these factors and if you compare the data in the way presented from here to here, you get that

effect.

I agree that an antibiotic effect would be nice to add to this graph and help explain the challenge a little more clearly that we're facing here.

BY MR. C. GORDON:

Q. Well, not just the antibiotic fact, but the anti-thromboprophylaxis fact, right?

MR. B. GORDON: That's just blood thinner.

THE WITNESS: Yeah. And a clinician would have to tell you what's relevant. I mean, you could put a lot of things in here too and say, Well, Larry was mopping the floors in this room for these days and that, and you can make this data so high dimensional you'll find all sorts of things that relate.

But I agree that the antibiotic piece is a real thing and some kind of an effect here, univariate effect presented in the same way as the other effects would be nice to have.

BY MR. C. GORDON:

Q. Were you ever made aware that at the beginning of the Bair Hugger period the laminar airflow system in one of the Wansbeck operating theaters was not functioning properly?

A. Not that I recall. I may have or may not, I don't know.

Q. Were you ever made aware of the fact that in 2008 and 2009 the Northumbria Trusts were repeatedly advised by the National Health Service that their SSI rates for orthopedic procedures made them a high outlier compared to other trusts in the -- in the UK?

A. I had heard they were having infection problems, I was not sure of the details.

Q. Did anyone ever tell you that as a result of those infection problems, they instituted a wide range of infection controlled procedures?

MR. B. GORDON: Object to form, lack of foundation, calls for speculation.

THE WITNESS: No, I don't know the exact procedures they implemented.

BY MR. C. GORDON: